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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,719	10/09/2001	Dusan Ninkov	12996.5USU1	7844

23552 7590 02/25/2004

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EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,719	NINKOV, DUSAN	
	Examiner	Art Unit	
	Clinton Ostrup	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/03/2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in this application.

Priority

Priority to Provisional US Application Numbers 60/238,501, filed October 6, 2000, 60/247,157, filed November 10, 2000, 60/277,121, filed March 19, 2001, and 60/288,531 filed May 3, 2001, has been acknowledged.

Response to Applicant's Arguments/Amendment

Claim Objections

Applicant's amendment filed December 3, 2003, has made the objection of claim 8, moot. Therefore, the said objection has been withdrawn.

Claim Rejections - 35 USC § 112

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 5, 8-10, 13-13, and 15-18 under 35 under 35 USC § 112, second paragraph, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Double Patenting

Applicant's amendment filed December 3, 2003, which cancelled claim 3, makes the double patenting rejection of claim 3, moot. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 1 and 4-20, as being unpatentable under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1-10 and 20-23 of U.S. Patent No. 6,414,036 has not made the said rejection, moot.

Although applicants chose to withhold their response to this rejection until allowable subject matter has been indicated, all reasonable rejections are made. Therefore, this rejection has been MAINTAINED for the reasons set forth in the Office Action mailed July 3, 2003 and those found below.

Claim Rejections - 35 USC § 102

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 1, 4, and 11 under 35 U.S.C. 102(b), as being anticipated by The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck), have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 1 and 19-20 under 35 U.S.C. 102(b), as being anticipated by Avery's Drug Treatment, 4th Edition, Chapter 31, pp. 1455-1509 (Avery), have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 1 and 19-20 under 35 U.S.C. 102(b), as being anticipated by Ropapharm B.V., EP 0904780A1 (Ropapharm), have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 1, 4, 8-9, 12, and 14-20 under 35 U.S.C. 103(a), as being unpatentable over Ropapharm B.V., EP 0904780A1 (Ropapharm) and further in view of Avery's Drug Treatment, 4th Edition, Chapter 31, pp. 1455-1509 (Avery), have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 1, 2, 4, and 10-11 under 35 U.S.C. 103(a), as being unpatentable over The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck) and common knowledge in the art, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed December 3, 2003, to the rejection of claims 3 and 13 under 35 U.S.C. 103(a), as being unpatentable over Ropapharm B.V., EP 0904780A1 (Ropapharm) and further in view of Remington's Pharmaceutical Sciences, Fifteenth Edition, 1975, pp.1405-1412, have been fully considered. However, Applicant's arguments are not found convincing.

Therefore, the said rejection has been **MAINTAINED** as applied to claim 13 and is being applied to claims 1, 4, 8-9, and 19-20 for the reasons set forth in the Office Action mailed July 3, 2003 and those found below.

Applicant argues that claim 1 requires that the organic phenol is reacted with at least one Group I salt, whereas Remington teaches that the sodium chloride or dextrose is added in order to adjust the isotonisity of the injectible formulation, and that these are

two different processes that create two different products. Applicant further argues that when the organic phenolic compound is reacted with a Group I salt, it is chemically modified (as compared to the formation of a solution).

First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the chemical modification of the organic phenolic compound, particularly the deprotonation of the organic phenolic compound, which then associates with the Group I cation from the Group I salt) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Secondly, absent unexpected results, it would be reasonable to expect that a pharmaceutical composition comprising Carvacrol (isopropyl o-cresol) and/or Thymol (isopropyl-cresol), water, Emulgator 686 and polysorbate, in solution, as taught by Ropapharm, when adjusted for isotonisity using either sodium chloride or dextrose, as taught by Remington's, would react with one another because of the species would be solvated in solution.

Maintained Claim Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 20-23 of U.S. Patent No. 6,414,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to pharmaceutical compositions, comprising the same ingredients, in the same amounts and for the same purpose. Instant claim 1 requires a pharmaceutical composition for treating an infection with an antimicrobial compound and a pharmaceutically acceptable carrier, and claim 1 of U.S. Patent No. 6,414,036 requires a pharmaceutical composition comprising an antimicrobial compound, wherein said antimicrobial compound comprises an organic phenolic compound chemically reacted with a Group I salt, and a pharmaceutically acceptable carrier for treating a microbial infection. Instant claim 1 teaches the antimicrobial as an organic phenolic compound and claims 4-7, and 15-18 teach reacting the antimicrobial as being base reacted.

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of claims 1-10 and 20-23 of 6,414,036 to form the instantly claimed pharmaceutical composition of claims 1 and

4-20, because of the reasonable expectation that such modifications would produce a pharmaceutical composition with desired antimicrobial activities.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims under 35 U.S.C. 103(a) as being unpatentable over Ropapharm B.V., EP 0904780A1 (Ropapharm) and further in view of Remington's Pharmaceutical Sciences, Fifteenth Edition, 1975, pp.1405-1412.

Ropapharm teaches a pharmaceutical composition in the form of a solution comprising Carvacrol (isopropyl o-cresol) and/or Thymol (applicants refer to Thymol as isopropyl-cresol), water, Emulgator 686 and polysorbate. See: page 3, col. 1, line 50 – col. 2, line 17. The reference teaches the pharmaceutical compositions as being suitable for the treatment of diseases caused by *Salamona* spp., *Pasteurella* spp., *E. coli*, *Vibrio coli*, etc. See: page 2, col. 1, line 55 – col. 2, line 5. The reference teaches the active ingredient in the form of thymol and/or carvacrol is present in an amount of 1-10% by weight, based on the total weight of the formulation. See: page 2, col. 2, lines 49-56.

Therefore, the reference teaches the specific antimicrobial compounds of instant claims 1 and 4 for the treatment of poultry, including turkeys as claimed in claim 19, and the use of said composition in as injectible solution comprising both thymol and carvacrol in amounts which overlap those claimed in instant claims 8-9 and 12, for the treatment of diseases caused by infections of the bacterial of claim 20. However, the

primary reference lacks the sodium chloride of instant claim 13, which qualifies as a Group I salt, as claimed instantly in claim 1.

Remington's teaches that a knowledge of colligative properties of solutions is essential for one to understand fully the principles involved in rendering intravenous solutions isotonic with blood serum...to produce less shock and less irritation than those which are hypotonic or hypertonic, and present-day practice recognizes the desirability of making the necessary adjustments whenever possible. Finally, the secondary reference teaches that the usual practice is to add either sodium chloride or dextrose to adjust hypotonic intravenous solutions to isotonicity. See: page 1405, col. 1, line 1 – page 1406, col. 1, line 34.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the isotonicity of the injectible formulation of Ropapharm by adjusting the tonicity of the solution using sodium chloride, the salt which is usually used for adjusting tonicity of injectible solutions because of the reasonable expectation that sodium chloride would adjust the formulation, to produce less shock and less irritation.

New Claim Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ropapharm B.V., EP 0904780A1 (Ropapharm) and further in view of Remington's

Pharmaceutical Sciences, Fifteenth Edition, 1975, pp.1405-1412 as applied to claims 1, 4, 8-9, 13 and 19-20 above, taken together with The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck) and common knowledge in the art.

The combined references above teach a solution comprising Carvacrol (isopropyl o-cresol) and/or Thymol (isopropyl-cresol), water, Emulgator 686 and polysorbate, which is adjusted for isotonisity using either sodium chloride or dextrose, however, the combined references lack the specific oils of claims 10-11.

The Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck). Merck teaches 1 gram of Thymol dissolves in 1.7 ml olive oil at 25 degrees. Since this is a claim to a composition, and the intended use of said composition is not given patentable weight unless it results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since Merck teaches the specifically claimed antimicrobial compound in the specifically claimed pharmaceutically acceptable carrier, it meets the limitations of instant claims 11. It is common knowledge that vegetable oil is a cheap, easily obtained alternative to olive oil.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the solution comprising Carvacrol (isopropyl o-cresol) and/or Thymol (isopropyl-cresol), water, Emulgator 686 and polysorbate, which is adjusted for isotonisity using either sodium chloride or dextrose, by adding olive oil as suggested by Merck, or by using a cheaper, easily obtained vegetable oil, because of

the reasonable expectation of obtaining an injectible pharmaceutical composition, comprising a readily available pharmaceutically acceptable carrier, which has the desirable property of solubilizing thymol.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-0582. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Clinton Ostrup
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Art Unit 1614

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